



UNITED STATES ENVIRONMENTAL PROTECTION
AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

MEMORANDUM

Date: 7/14/2020

Subject: Efficacy Review for TM70,
EPA File. No. 833-RI,
DP Barcode: 457703
E-submission: 47160

From: Marcus Rindal
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: 8/1/2020

Thru: Cesar E. Cordero
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: 8/05/2020

To: Jacqueline Hardy RM34/Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Alex C. Fergusson, LLC
550 Development Avenue
Chambersburg, PA 17201

Formulation from the Label:

| <u>Active Ingredient</u> | <u>% by wt.</u> |
|--------------------------------|-----------------|
| Ethyl alcohol | 66.59 % |
| Isopropanol | 3.73% |
| <u>Other Ingredients</u> | 29.68% |
| Total | 100.00% |

I. BACKGROUND

Product Description (as packaged and applied): Ready to use, applied as spray, wipe, and immersion applications

Submission Type: New product registration.

Requested Action: The registrant is submitting a “Me-Too” application for a new end use product registration for TM 70. The product contains the active ingredients ethyl alcohol and isopropanol for use as a food-contact, no-rinse sanitizing spray on hard, non-porous surfaces in industrial, commercial, and retail markets. The formulation, manufacturing methods, etc. are claimed to be substantially similar to EPA Reg. No. 73232-4, Alpet D2 Quat-Free Surface Sanitizer.

Documents Submitted for Consideration:

- A letter to EPA (dated February 21, 2020)
- Application for Pesticide Registration (EPA form 8570-1)
- Confidential Statement of Formula (EPA form 8570-4), dated February 21, 2020
- Certification with Respect to Citation of Data (EPA form 8570-34)
- Data Matrix (EPA Form 8570-35)
- 3 efficacy studies (MRID Nos. 51060104 - 51060106)
- Proposed product label dated 2/21/2020.

USE DIRECTIONS SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD NON-POROUS FOOD CONTACT SURFACES

TM 70 is recommended for use as a sanitizer on food contact surfaces such as processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard nonporous food contact surfaces. Preclean surfaces prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe, sponge, or by total immersion. Surfaces must be thoroughly wetted.

Treated surfaces must remain wet for 60 seconds.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by sponge, wipe, brush or coarse spray. Surfaces must remain wet for at least one minute followed by adequate draining and air-drying. Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment can be sanitized by immersion with this product. Always use fresh solution for this purpose.

TM 70 is an effective sanitizer against *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 11299), *Listeria monocytogenes* (ATCC 19117), and *Salmonella enterica* (ATCC 10708) on hard non-porous food contact surfaces. Treated surfaces must remain wet for 60 seconds. Allow to air dry. Do not rinse.

FOOTWEAR SANITIZER

TM 70 is recommended as a sanitizer for use on outside surfaces of non-porous waterproof footwear such as rubber boots and work boots. Preclean footwear prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe or total immersion to ensure exposure to sanitizer for at least 10 seconds. Allow surfaces to air dry.

SANITIZING NON-POROUS WATERPROOF GLOVES

TM 70 is recommended as a sanitizer for use on nonporous, waterproof gloves. Preclean gloves prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe or total immersion to ensure exposure to sanitizer for at least 60 seconds. Allow surfaces to air dry. Do not rinse

II. SYNOPSIS OF SUBMITTED EFFICACY STUDIES

| | | | | | | |
|--|--|---|-------------------------------|-------------|-------------|---------------|
| 1. | MRID | 51060104 | Study Completion Date: | | 9/6/18 | |
| Experimental Start Date | | 8/20/18 | | | | |
| Study Objective | | Food Contact Sanitizer | | | | |
| Study Title | | Germicidal and Detergent Sanitizing Action of Disinfectants | | | | |
| Testing Lab, Lab Study ID | | Accuratus Laboratory, Project ID # A26089 | | | | |
| Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+ | | <i>Staphylococcus aureus</i> (ATCC 6538) <i>Escherichia coli</i> (ATCC 11229) 1 mL of suspension | | | | |
| Test Method | | AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method; Protocol No. AFC01040918. GDST.2 | | | | |
| Application Method | | Suspension | | | | |
| Test Substance Preparation | Name/ID | TM 70 | | | | |
| | Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 | Batch# 050918E1, 050918E2, 050918E3 Tested concentration: LCL | | | | |
| | Preparation | Ready-to-use | | | | |
| Soil load | | No organic soil load | | | | |
| Carrier type, # per lot | | -- | | | | |
| Test conditions | | Contact time | 30 sec. | Temp | 25.0-26.0°C | RH N/A |
| Incubation Conditions | | 24-30 hours at 35±2°C | | | | |
| Neutralizer | | 1 mL test substance culture + 9 mL of neutralizer (Lethen Broth + 0.14% Lecithin + 1.0% Tween 80) | | | | |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | No protocol amendments or deviations were indicated. | | | | |

| | | | | | | | |
|--|--|--|-------------------------------|-------------|--------|-----------|-----|
| 2. | MRID | 51060105 | Study Completion Date: | | 9/6/18 | | |
| Experimental Start Date | | 8/22/18 | | | | | |
| Study Objective | | Food Contact Sanitizer | | | | | |
| Study Title | | Germicidal and Detergent Sanitizing Action of Disinfectants | | | | | |
| Testing Lab, Lab Study ID | | Accuratus Laboratory, Project ID # A26092 | | | | | |
| Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+ | | <i>Listeria monocytogenes</i> (ATCC 19117) 1 mL of suspension | | | | | |
| Test Method | | AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method; Protocol No. AFC01040918.GDST.3 | | | | | |
| Application Method | | Suspension | | | | | |
| Test Substance Preparation | Name/ID | TM 70 | | | | | |
| | Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 | Batch# 050918E4, 050918E5 Tested concentration: LCL | | | | | |
| | Preparation | Ready-to-use | | | | | |
| Soil load | | No organic soil load | | | | | |
| Carrier type, # per lot | | -- | | | | | |
| Test conditions | | Contact time | 30 sec. | Temp | 25±1°C | RH | N/A |
| Incubation Conditions | | 24-30 hours at 35±2°C | | | | | |
| Neutralizer | | 1 mL test substance culture + 9 mL of neutralizer (BHI Broth + 0.14% Lecithin + 1.0% Tween 80) | | | | | |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | No protocol amendments or deviations were indicated. | | | | | |

| | | | | | | | |
|--|--|--|-------------------------------|-------------|--------|-----------|-----|
| 3. | MRID | 51060106 | Study Completion Date: | 9/6/18 | | | |
| Experimental Start Date | | 8/23/18 | | | | | |
| Study Objective | | Food Contact Sanitizer | | | | | |
| Study Title | | Germicidal and Detergent Sanitizing Action of Disinfectants | | | | | |
| Testing Lab, Lab Study ID | | Accuratus Laboratory, Project ID # A26093 | | | | | |
| Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+ | | <i>Salmonella enterica</i> (ATCC 10708) 1 mL of suspension | | | | | |
| Test Method | | AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method; Protocol No. AFC01040918.GDST.4 | | | | | |
| Application Method | | Suspension | | | | | |
| Test Substance Preparation | Name/ID | TM 70 | | | | | |
| | Lots <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 | Batch# 050918E4, 050918E5 Tested concentration: LCL | | | | | |
| | Preparation | Ready-to-use | | | | | |
| Soil load | | No organic soil load | | | | | |
| Carrier type, # per lot | | -- | | | | | |
| Test conditions | | Contact time | 30 sec. | Temp | 25±1°C | RH | N/A |
| Incubation Conditions | | 24-30 hours at 35±2°C | | | | | |
| Neutralizer | | 1 mL test substance culture + 9 mL of neutralizer (Lethen Broth + 0.14% Lecithin + 1.0% Tween 80) | | | | | |
| Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.) | | No protocol amendments or deviations were indicated. | | | | | |

III. RESULTS

| Hard, Non-Porous Food Contact Surface Sanitizer | | | | | | | |
|---|----------|--------------------------|--|-----------|---------------------|-----------------------------|-----------------------------------|
| Contact Time | MRID No. | Temp. & RH | Organism | Results | | | Numbers Control Average CFU/mL |
| | | | | Batch No. | Average CFU/carrier | Log ₁₀ Reduction | |
| Suspension, 0% serum | | | | | | | |
| 30 sec. | 51060104 | 25°C, RH not provided | <i>Staphylococcus aureus</i> (ATCC 6538) | 050918E1 | <1 CFU/mL | >7.40 | 2.5 x 10 ⁷ |
| | | | | 050918E2 | <1 CFU/mL | >7.40 | |
| | | | | 050918E3 | <1 CFU/mL | >7.40 | |
| | | | <i>Escherichia coli</i> (ATCC 11229) | 050918E1 | <1 CFU/mL | >7.49 | 3.1 x 10 ⁷ |
| | | | | 050918E2 | <1 CFU/mL | >7.49 | |
| | | | | 050918E3 | <1 CFU/mL | >7.49 | |

| Hard, Non-Porous Food Contact Surface Sanitizer | | | | | | | |
|---|----------|--------------------------|---|-----------|---------------------|-----------------------------|-----------------------------------|
| Contact Time | MRID No. | Temp. & RH | Organism | Results | | | Numbers Control Average CFU/mL |
| | | | | Batch No. | Average CFU/carrier | Log ₁₀ Reduction | |
| Suspension, 0% serum | | | | | | | |
| 30 sec. | 51060105 | 25°C, RH not provided | <i>Listeria monocytogenes</i> (ATCC 19117) | 050918E4 | <1 CFU/mL | >7.81 | 6.5 x 10 ⁷ |
| | | | | 050918E5 | <1 CFU/mL | >7.81 | |
| 30 sec. | 51060106 | 25°C, RH not provided | <i>Salmonella enterica</i> (ATCC 10708) | 050918E4 | <1 CFU/mL | >7.79 | 6.2 x 10 ⁷ |
| | | | | 050918E5 | <1 CFU/mL | >7.79 | |

IV. CONCLUSIONS

| MRID #49253603 - 49253618 | | | | | | | | |
|---------------------------|--------------------------------|---------------------------|------------------------------------|--------------|-----------|--|---|---------------------------------|
| MRID # | Claim | Surface Type | Application Method(s) and Dilution | Contact Time | Soil load | Conditions (temp & relative humidity [RH]) | Organism(s) | Data support tested conditions? |
| 51060104 | Food contact surface sanitizer | Hard, non-porous surfaces | Suspension | 30 sec. | 0% | 25°C, RH not provided | <i>Staphylococcus aureus</i> (ATCC 6538), <i>Escherichia coli</i> (ATCC 11229) | Yes |
| 51060105 | Food contact surface sanitizer | Hard, non-porous surfaces | Suspension | 30 sec. | 0% | 25°C, RH not provided | <i>Listeria monocytogenes</i> (ATCC 19117) | Yes |
| 51060106 | Food contact surface sanitizer | Hard, non-porous surfaces | Suspension | 30 sec. | 0% | 25°C, RH not provided | <i>Salmonella enterica</i> (ATCC 10708) | Yes |

V. LABEL RECOMMENDATIONS (for label dated 2/21/2020)

1. The proposed label claims are **acceptable** regarding the use of the product, TM 70, EPA Reg. File No. 833-RI, as a ready-to-use food contact surface sanitizer against the following organisms for use on hard, non-porous surfaces at room temperature and at a 1-minute contact time with precleaning instructions.

Escherichia coli (ATCC 11229)
Staphylococcus aureus (ATCC 6538)
Listeria monocytogenes (ATCC 19117)
Salmonella enterica (ATCC 10708)

These claims **are supported** by the applicant's data.

2. The proposed label claims are **NOT acceptable** regarding the use of the product, TM 70, EPA Reg. File No. 833-RI, as a ready-to-use footwear sanitizer against the following organisms for use on clean, outside surfaces of nonporous waterproof footwear at a **10- second contact time** when applied as a spray, wipe, or by immersion:

Escherichia coli (ATCC 11229)
Staphylococcus aureus (ATCC 6538)
Listeria monocytogenes (ATCC 19117)
Salmonella enterica (ATCC 10708)

These claims **are not supported** by the applicant's data, specifically the 10 seconds contact time (See label comment below).

3. **Make the following changes to the proposed label:**
 - a. On page 3 of the proposed label, delete the section titled "FOOTWEAR SANITIZER" as this claim is not acceptable since the 10 seconds contact time is not supported by the submitted efficacy data.